REMARKS

Prior to this Response, a Final Office Action rejecting all claims was mailed July 14, 2006, responding to Applicant's amendments and arguments made in response to a prior Office Action mailed September 7, 2005.

Claims 1, 11, and 12 were finally rejected under 35 U.S.C. § 103(a) as unpatentable over EP 0372127A1 to L'Esperance or US 6,042,594 to Hellenkamp.

Claims 2 and 13 were finally rejected under § 103(a) as unpatentable over L'Esperance or Hellenkamp, in combination with US 4,173,980 to Curtin.

Claims 3-10 and 14-21 were finally rejected under § 103(a) as unpatentable over L'Esperance or Hellenkamp, in combination with US 5,591,174 to Clark, et al.

Claims 3-10 were finally rejected under § 103(a) as unpatentable over L'Esperance or Hellenkamp, and Curtin, in combination with Clark.

Claim 22 is new.

In this Response, regarding the Claims, all rejections are respectfully traversed, and Applicant requests continued examination to consider new evidence in the form of an Affidavit made under C.F.R. 1.132, and new argument addressing the Affidavit and responsive to Examiner's rejection. In addition, new claim 22 has been added for clarity. Support for new claim 22 is found in the specification at page 4, ll. 11-14; and Figure 4.

No amendment made was related to the statutory requirements of

patentability unless expressly stated herein. No amendment made was for the purpose of narrowing the scope of any claim, unless Applicant has argued herein that such amendment was made to distinguish over a particular reference or combination of references.

Claims 1-22 are now pending in the present application. Reconsideration is requested. In addition to the new evidence, and new claim, the Applicant makes the following remarks regarding individual issues:

THE APPLICANT'S TIME TO RESPOND

The last Office Action was mailed on July 14, 2006. The three-month initial deadline for responding without having to pay a penalty fee ended on October 14, 2006. The Applicant hereby encloses a 3-month small entity extension fee. The initial deadline is thus extended to January 14, 2007. In determining whether this document is timely filed, the Patent Office is asked to note the Applicant's Certificate of Mailing in conjunction with 37 C.F.R. § 1.8.

THE SECTION 103(A) OBVIOUSNESS REJECTIONS

The Examiner rejected Claims 1, 11, and 12 under 35 U.S.C. § 103(a) as being unpatentable over L'Esperance or Hellenkamp, and further in view of U.S. Patent 5,133,726 to Ruiz (incorporated by reference in Hellenkamp), newly asserted in the Final Rejection. Claims 2 and 13 were rejected under § 103(a) as unpatentable over L'Esperance or Hellenkamp, combined with US 4,173,980 to Curtin. Claims 3-10 and 14-21 were rejected under § 103(a) as unpatentable over L'Esperance or Hellenkamp, combined with US 5,591,174 to Clark, et al. Claims 3-10 were rejected under § 103(a) as unpatentable over L'Esperance or

Hellenkamp, and Curtin, combined with Clark.

Applicant respectfully reasserts his previous traversal regarding these rejections, and directs the Examiner to the newly submitted affidavit of Dr. Brian Will, and arguments below.

A. Claims 1, 11, and 12

The combination of L'Esperance and Hellenkamp does not disclose the combinations of elements recited in independent Claims 1, 11 and 12, nor has any reference been asserted teaching or suggesting such modification, and therefore the Examiner has not established a prima facie case of obviousness. None of the references discloses apparatus or methods for an eye fixation apparatus utilizing criss-crossing channels on a convex bottom contact portion, without use of a vacuum annulus, nor do they disclose apparatus or methods capable of repositioning a vacuum-based eye fixation apparatus after vacuum has been applied initially. Nor has the Examiner identified any suggestion, teaching or motivation to modify the cited references to achieve Applicant's inventions other than Applicant's own disclosure, which is considered impermissible hindsight. Reference to Dr. Brian Will's Affidavit provides explanation of the unique features of the present invention, and the significant differences from the prior art cited by the Examiner.

The Examiner states, "Both L'Esperance (EP '127) and Hellenkamp teach a device and method as claimed except for the criss-cross passages." *OA July 14, 2006, at page 5.* The criss-cross channels, providing alternating lands and grooves, are fundamental to the present invention, and are not disclosed by the

cited references. L'Esperance and Hellenkamp do not disclose means for fixing an eye for surgery other than a hollow annulus. A hollow annulus has specific disadvantages not appreciated by either L'Esperance nor Hellenkamp which are addressed by the present invention, as pointed out by the accompanying Affidavit of Dr. Will. The Examiner also asserts that "to discontinue vacuum and reposition the apparatus if it is not centered on the cornea [is obvious], since proper positioning of the corneal flap is critical..." *OA July 14, 2006, at p. 5.* The apparatus and methods of the references cited by the Examiner actually *prevent* discontinuation of vacuum and repositioning of the apparatus due to the negative effects of using a hollow annulus to apply vacuum, as explained by the Affidavit of Dr. Will. Thus, the Examiner's arguments regarding obviousness actually demonstrate the unobviousness of using a system of criss-cross channels providing alternating lands and grooves. In addition, L'Esperance and Hellenkamp retain the significant disadvantage that they require lid speculum during most procedures (due to the inherently high profile of the hollow annulus), especially for patients with narrow ocular orbits, and they contain no teachings to indicate a solution. Other disadvantages of the L'Esperance and Hellenkamp references, which are addressed by the present invention, are made apparent by the accompanying Affidavit of Dr. Will.

L'Esperance applies suction through a porous membrane via an annular chamber above the porous membrane. *See L'Esperance '127 at col.4, ll.26-34.* This is the only method taught by L'Esperance '127 and its related applications. *See e.g. L'Esperance, Jr. '148 (also cited by Examiner) and L'Esperance, U.S.*

4,665,913, incorporated by reference into L'Esperance '148. All porous materials are subject to clogging, a simple fact of nature which Dr. Will has confirmed with real-world experience in performing thousands of eye surgeries. Examiner has cited nothing in L'Esperance or any other reference suggesting special properties which render L'Esperance's porous membrane not subject to clogging. The Hellenkamp reference, cited by Examiner, specifically discusses the problem of mucus accumulation which can occlude vacuum components, during procedures and after hardening, and which requires special cleaning procedures to remove. *See Affidavit of Dr. Will ¶ 5.h.* The removable vacuum member in Hellenkamp is specifically intended as an attempt to address this problem, among others, but it is an incomplete solution at best. *See Hellenkamp, col. 5, ll. 43-5.*

The difficulty in cleaning is discussed as a general hindrance which can reduce the patient turnover rate. *See Hellenkamp, col. 3, l. 45 – col. 4, l. 12.* The same difficulties with clogging and effective cleaning described in Hellenkamp are magnified in a porous membrane as taught by L'Esperance. Additional drawbacks include higher risk of patient cross-contamination with viral, bacterial and prion material. *See Affidavit of Dr. Will ¶ 5.h.* The present invention provides a relatively smooth and impermeable surface with shallow cross-connected channels which are easily cleaned using conventional methods, thereby extending the life of the apparatus. The cross-connection prevents loss of vacuum from occlusion of any single channel due to buildup.

Additionally, the hollow annulus designs inherent to L'Esperance and Hellenkamp require the use of a lid speculum on patients with narrow ocular

orbits. The use of lid specula causes undesired negative side effects which have been documented, and are an ever increasing problem as procedures such as LASIK become more widespread. Dr. Will's Affidavit specifically addresses the complications caused by conventional hollow annulus apparatus. The use of criss-cross channels with alternating lands and grooves in the present invention avoids the need for lid speculum even in patients with narrow orbits because it allows a lower profile device. The Examiner has failed to point to any reference which teaches criss-cross vacuum channels, creating a low profile apparatus which can fit underneath the eyelids, obviating the need for a lid speculum during surgery. All of the art cited by Examiner relies upon an annular design necessitating a vault, with the exception of Ruiz, newly asserted by Examiner, which does not teach the use of a vacuum fixation apparatus at all and so does not support the rejection.

Examiner, in his previous Office Action, has placed himself in the strange, and improper, position of advocating for the prior art. Applicant does not argue that the prior art cited lacks utility or is non-functional, but the present invention provides unobvious improvements over the cited references which achieve greater accuracy and less discomfort from patients, while making laser keratome procedures more economical for practitioners. Further, if the Examiner relies on personal knowledge to assert that:

(1) L'Esperance and Hellenkamp are not subject to clogging or occlusion;

(2) neither L'Esperance nor Hellenkamp cause damage to the

cornea/conjunctiva surface when vacuum is applied and removed; and,

(3) that use of high profile hollow annular rings as taught by the Examiner's cited references does not cause complications and discomfort to patients;

then the Examiner is required to provide an affidavit explaining the basis of such knowledge. *See* MPEP 2144.03(A) [R-1]:

> "It is never appropriate to rely solely on "common knowledge" in the art without evidentiary support in the record, as the principal evidence upon which a rejection was based. *Zurko*, 258 F.3d at 1385, 59 USPQ2d at 1697 ("[T]he Board cannot simply reach conclusions based on its own understanding or experience-or on its assessment of what would be basic knowledge or common sense. Rather, the Board must point to some concrete evidence in the record in support of these findings."). While the court explained that, "as an administrative tribunal the Board clearly has expertise in the subject matter over which it exercises jurisdiction," it made clear that such "expertise may provide sufficient support for conclusions [only] as to peripheral issues." *Id.* at 1385-86, 59 USPQ2d at 1697. As the court held in *Zurko*, an assessment of basic knowledge and common sense that is not based on any evidence in the record lacks substantial evidence support. *Id.* at 1385, 59 USPQ2d at 1697. See also *In re Lee*, 277 F.3d 1338, 1344-45, 61 USPQ2d 1430, 1434-35 (Fed. Cir. 2002) (In reversing the Board's decision, the court stated "'common knowledge and common sense' on which the Board relied in rejecting Lee's application are not the specialized knowledge and expertise contemplated by the Administrative Procedure Act. Conclusory statements such as those here provided do not fulfill the agency's obligation... The board cannot rely on conclusory statements when dealing with particular combinations of prior art and specific claims, but must set forth the rationale on which it relies."

Further, "While 'official notice' may be relied on, these circumstances should be rare when an application is under final rejection..." MPEP 2144.03(A) [R-1].

> "It would <u>not</u> be appropriate for the examiner to take official notice of facts without citing a prior art reference where the facts asserted to be well known are not capable of instant and unquestionable demonstration as being well-known. For example, assertions of technical facts in the areas of esoteric technology or specific knowledge of the prior art must always be supported by citation to some reference work recognized as

> standard in the pertinent art. *In re Ahlert*, 424 F.2d at 1091, 165 USPQ at 420-21. See also *In re Grose*, 592 F.2d 1161, 1167-68, 201 USPQ 57, 63 (CCPA 1979)"

MPEP 2144.03(A) (emphasis original). "If the examiner is relying on personal knowledge to support the finding of what is known in the art, the examiner must provide an affidavit or declaration setting forth specific factual statements and explanation to support the finding. *See* 37 C.F.R. 1.104(d)(2)." MPEP 2144.03(C) [R-1]. Furthermore, Section 103 requires analysis of a claimed invention as a whole:

> "Focusing on the obviousness of substitutions and differences, instead of on the invention as a whole, is a legally improper way to simplify the often difficult determination of obviousness."

The Gillette Co. v. S.C. Johnson & Son Inc., 16 USPQ2d 1923 (Fed. Cir. 1990).

The foundational facts for the prima facie case of obviousness are: (1) the scope and content of the prior art; (2) the difference between the prior art and the claimed invention; and (3) the level of ordinary skill in the art. Graham v. John Deere Co., 383 U.S. at 17-18; Miles Lab., Inc. v. Shandon Inc., 27 USPQ2d 1123, 1128 (Fed. Cir. 1993). The Affidavit of Dr. Will accompanying this RCE provides objective evidence of the difference between the prior art and the claimed invention which must be credited. Regarding the use of criss-cross channels, incorporated into all claims through independent claims 1, 11 and 22, no references cited by the Examiner include criss-cross channels. The use of criss-cross channels minimizes distortion of the eye lens which causes less than optimal correction to patients' vision. The criss-cross channels prevent or minimize damage to the cornea, sclera and conjunctiva which has been a documented problem in LASIK and other keratome procedures using apparatus

such as relied upon by the Examiner. The criss-cross channels permit a low-profile device which can fit under patients' eye lids, obviating the need for a lid speculum, thereby reducing complications in patient recovery and reducing obstructions during surgery. These complications are especially relevant for patients with narrow ocular orbits. Dr. Will's Affidavit also provides citation to references which provide objective evidence to back up his explanations of the differences and advantages of his invention over the prior art demonstrating the unobviousness of the claims. *See Affidavit of Dr. Will* ¶¶ *7-8*.

Moreover, "It is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one skilled in the art." Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc., 230 USPQ 416 (Fed. Cir. 1986). The Examiner's rejections amount to using that which Dr. Will teaches in his patent against him by selectively choosing elements of several references and combining them without evidence of a suggestion, teaching or motivation to combine – at which point the Examiner argues it would be obvious to further modify the combined elements of the various references to achieve the claimed invention, again without any suggestion, teaching or motivation. This is exactly the type of hindsight analysis that is so often rejected in court decisions.

Both Hellenkamp and L'Esperance teach vacuum rings with annular vaults requiring the use of lid specula causing greater discomfort for patients. L'Esperance '172 (cited by Examiner), which is a continuation-in-part of

Application 891,285 issued as L'Esperance '148 (also cited by Examiner), specifically teaches the requirement of using a lid speculum and can therefore be viewed as teaching away from apparatus and methods which do not require such. *See L'Esperance '172, col.3, ll.50-59.* "A prior art reference may be considered to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." Monarch Knitting Machinery Corp. v. Sulzer Morat GmbH, 45 USPQ2d 1977 (Fed. Cir. 1998). *See also* The Dow Chemical Co. v. U.S.,18 USPQ2d 1657 (Ct. Cl. 1990). The use of criss-crossed channels with alternating lands and grooves, a recited element in all claims of the present invention, eliminates the need for annular vaults thereby creating a lower profile device. This lower profile eliminates the need for a lid speculum in most cases, and is more comfortable for patients, especially those with narrow or tight lid openings. This fundamentally distinguishes the present claims from L'Esperance.

Moreover, as shown above, Hellenkamp teaches away from the claimed invention. In effect, "teaching away" is a more pointed and probative form of skepticism expressed in the prior art. Id. Teaching away from the prior art supports a conclusion of nonobviousness.

Examiner incorrectly states, at page 3, that there is no disclosure in the Application relating to holding the corneal surface flat, without displacement into the criss-cross vacuum channels. Examiner is directed to the original specification, which has not been amended, at page 6, lines 12-20:

> "When placed on the eye, with the contact portion **14** contacting directly upon the eye and encircling the cornea, the criss-crossing channels **16** are upon the eye globe conjunctiva. Vacuum port **18** communicates with channels **16** such that vacuum pressure exerted at the vacuum port **18** creates vacuum pressure in the criss-crossing channels **16**, *sucking the eye globe conjunctiva attached to the sclera flush against the contact portion **14***. This fixates the eye. The criss-crossing channels **16** work to oppose the suction created by each other, such that *the eye glove conjunctiva attached to the sclera, is spread taut between the channels **16**, instead of being sucked upon into a particular channel*."

(emphasis added). Examiner is further directed to the Specification's "Summary of the Invention", at page 4, lines 11-21, which recites decreased trauma to the ocular surface and the ability to more easily reposition the fixation device after vacuum has once been applied as specific advantages of the present invention. Examiner is also directed to Dr. Will's accompanying Affidavit for further evidence in this regard. In contrast, the Hellenkamp reference relied on by the Examiner specifically acknowledges that the cornea is displaced into the hollow vacuum ring to contact the surface of the vacuum enhancer. *Hellenkamp at col.9, ll. 23-43*. Applicant respectfully requests the Examiner provide record evidence to support his incorrect factual assertion that the present invention does not draw the cornea surface to contact against the flat land between the criss-cross channels, rather than into the channels themselves, as claimed and described.

Additionally, the use of criss-cross channels (a recited element of each claim) avoids the problem of clogging which porous surfaces (such as taught in L'Esperance) are subject to. The use of channels also permits a lower profile than devices using a porous surface can achieve because there is no need for the vacuum annulus above the porous surface (as taught in L'Esperance). Thus, the present invention provides unobvious solutions to the problems inherent in

existing apparatus and methods.

Examiner incorrectly states, at page 3, that "with regard to Hellenkamp, applicant theorizes a problem with the reference, but does not associate it with any particular structure of the device." Applicant directs the Examiner to Applicant's response to prior Office Actions, and to the accompanying Affidavit of Dr. Will. Applicant has made clear that a significant disadvantage of existing designs such as Hellenkamp, Curtin, and others is that they rely on a hollow annular ring to apply vacuum, which causes the cornea surface to displace into the vault of the ring. The vacuum enhancer taught by Hellenkamp reduces this problem, but does not eliminate it. Applicant has also explained that the vault – inherent in the design of existing hollow annular rings, including Hellenkamp, Curtin and L'Esperance – creates the need for a lid speculum during procedures, which is generally eliminated by the low profile of the criss-cross channel design which is recited in all claims of the present invention. Applicant, by pointing out these specific drawbacks of existing apparatus and methods, does not argue that these references are inoperative or invalid, but merely that they are not perfect solutions. The present invention represents a significant improvement over existing apparatus and methods in many respects, discussed in detail in Dr. Will's Affidavit. The Examiner incorrectly implies that by claiming improvement over the existing art Applicant must thereby prove the existing art lacks utility.

B. Claims 2 and 13.

Dependent Claims 2 and 13 were rejected under § 103(a) as unpatentable over L'Esperance or Hellenkamp in combination with Curtin. Traversal with

respect to L'Esperance or Hellenkamp is reasserted regarding independent claims 1, 11 and 12 and further with regard to their combination with Curtin, which teaches a conventional hollow annular ring. *Curtin, col.5, ll. 46-51.* The Examiner asserts that "Curtin teaches the use of adjustment arms on eye fixation devices." *OA July 14, 2006, at p.5.* Applicant respectfully disagrees. Curtin specifically teaches that the rigid vacuum tube 128 holds annular ring 124 stationary over an eyeball, at which point the patient is provided a target to focus on which aligns the eye to the apparatus. Vacuum is applied to annular ring 124 which then "locks the ring arrangement 122 on the patient's eye when the patient's visual axis is aligned with the target." *Curtin, col.6, ll. 1-8; col. 7, ll. 29-39 & 63-68.* Curtin does not, alone nor in combination with other references cited, teach or suggest the use of adjustment arms connected to an eye fixation apparatus which permit adjustment of the apparatus to the eyeball prior to fixation, rather than having the eyeball align itself to a vacuum ring. Thus Curtin teaches exactly the opposite methodology of the current invention recited in claims 2, 13 and 22, which renders it less optimal than the current invention.

Dr. Will, in his affidavit, notes several advantages from the use of adjustment arms. *See Affidavit of Dr. Will ¶ 10.c.* Maneuvering the device is easier, and there is less chance that inadvertent contact will scratch the conjunctival surface or cause contamination. A person of skill in the art would not see the combination of Curtin with L'Esperance and/or Hellenkamp as teaching the present invention. Nor does any other reference cited teach the use of adjustment arms in conjunction with a vacuum ring eye fixation apparatus.

C. Claims 3-10 and 14-21

Dependent Claims 3 through 10 and 14 through 21 were rejected under § 103(a) as unpatentable over L'Esperance or Hellenkamp in combination with Clark et al. Traversal with respect to L'Esperance or Hellenkamp is reasserted regarding independent claims 1, 11 and 12, and further with regard to their combination with Clark et al. Clark is not directed to the positioning of surgical devices during surgery. The x-y adjustment taught by Clark relates to adjusting the platform of a microscope set upon a stable base, away from any surgical procedure, so as to permit the proper depth setting of a microkeratome blade to be used in surgery. Clark, even in combination with L'Esperance and Hellenkamp, does not teach or suggest the elements of translation guide members adjustably connected to an eye fixation apparatus during surgery (claims 3, 7, 14, 18 and 22), nor the additional elements of translation rods with adjustment knobs to provide fine control (claims 4, 8, 15, 19 and 22). Nor do the references, even in combination, teach the use of docking screws to dock surgical devices to translation guide members at all (see claims 5, 6, 9, 10, 16, 20, 21 and 22), much less translation guide members which are adjustably connected to an eye fixation apparatus during surgery.

As Dr. Will's Affidavit makes clear, the ability to adjust the fixation apparatus to the eyeball, rather than vice versa, provides for better adjustment and concentration properties during laser procedures. This adjustment capability is enhanced by the addition of lateral translation members directly to the eye fixation apparatus. Translation guide rods with knob adjusters allow precise

adjustments while requiring less manual dexterity than current apparatus and methods. The translation guide rods also prevent further distortion of the eyeball caused by forcing the eyeball into alignment with the surgical apparatus. The addition of docking screws to dock surgical apparatus, such as lasers or optical cones, directly to the eye fixation apparatus ensures even more precise alignment to achieve superior concentration properties in laser procedures.

D. Claims 3-10

Dependent Claims 3-10 were rejected under § 103(a) as unpatentable over L'Esperance or Hellenkamp and Curtin in combination with Clark et al. Traversal with respect to L'Esperance or Hellenkamp and Curtin is reasserted regarding claims 1 through 10, and further with regard to their combination with Clark et al. The cited references simply do not disclose the elements of the present invention. Clark does not in any way teach employing x- and y-axis adjustment mechanisms movably connected to eye fixation devices during surgery, as discussed above. Clark teaches only bench alignment of cutting devices, which devices are then used in ophthalmic surgery. The rigid vacuum arm taught in Curtin does not disclose, suggest, nor teach adjustment arms permitting adjustment of the eye fixation device to the eyeball, as opposed to adjusting the eyeball rigidly to the device. Examiner's additional reliance on Ruiz does not disclose the elements of the claim either. Ruiz teaches a geared cutting blade on a base which lacks the ability to fix the eye in space, and so still fails to disclose, even in combination, all of the elements of the rejected claims. Reference to Ruiz, Figure 10, also demonstrates the type of lens distortion

created by existing apparatus and methods which the present invention is specifically designed to avoid. The Examiner has not established a prima facie case of obviousness under Section 103(a).

In addition, Dr. Will's affidavit makes clear the differences between the present invention and the asserted references. X-Y adjustment ability and the use of docking screws for setting and adjusting surgical apparatus prevents further distortion of the eyeball caused by forcing the eyeball to alignment with the apparatus, rather than vice versa. It also eliminates the need for expensive and complicated software to adjust for laser offset. The claims are unobvious.

E. New claim 22

Claim 22 is newly submitted. Support for claim 22 is found in the Specification at page 4, ll. 11-14 and Fig. 4. Claim 22 additionally recites "An eye fixation apparatus comprising... wherein the eye fixation portion has a low-profile annular convex bottom contact portion..." The original Specification, at page 4, lines 11-14, describes a feature of the invention that "(1) functions without the need for a lid speculum; (a) low profile fits comfortably under the lids; (b) can more easily be used on patients with "tight lids" which are common to some races..." The arguments traversing rejections of apparatus claims 1-10 and method claims 11-21 are equally valid regarding the unobviousness of apparatus claim 22. Based on the above, claim 22 should be in condition for allowance.

CONCLUSION

The present invention improves the precision (and reliability) of positioning devices for keratome and LASIK procedures, reduces damage to the conjunctival

tissue, and makes the procedure more economical through the use of apparatus and methods which are more amenable to cleaning and reuse. The rejections are respectfully traversed as to claims 1 through 21. It is requested that the rejections be withdrawn. The present invention specifically addresses the limitations of apparatus and methods such as cited by Examiner. It is important to note that ophthalmic surgery is an art where seemingly minor changes have significant impact. For the foregoing reasons, reconsideration and allowance of claims 1 through 21 and new claim 22 of the application as amended is solicited.

The Examiner is encouraged to telephone the undersigned at (360) 750-9931 if it appears that an interview would be helpful in advancing the case. The Applicant respectfully submits that the rejection of the pending claims must be withdrawn, and that this application is in condition for allowance for all claims pending. Such is earnestly requested.

Respectfully submitted,

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